

Related Change Request (CR) #: 3984

MLN Matters Number: MM3984

Related CR Release Date: August 5, 2005

Related CR Transmittal #: 642

Effective Date: October 1, 2005

Implementation Date: October 3, 2005

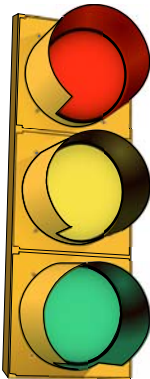
New Waived Tests Approved by the Food and Drug Administration (FDA) Under Clinical Laboratory Improvement Amendments (CLIA) of 1988

Note: This article was revised to contain Web addresses that conform to the new CMS web site and to show they are now MLN Matters articles. All other information remains the same.

Provider Types Affected

Providers/suppliers billing services to Medicare carriers

Provider Action Needed



STOP – Impact to You

This article includes information from Change Request (CR) 3984 which informs Medicare carriers of new tests granted waived status under CLIA by the FDA.

CAUTION – What You Need to Know

Since these tests are marketed immediately after their approval, Medicare carriers need to be aware of these new tests and update their files so your claims can be accurately processed.

GO – What You Need to Do

See the Background Section of this article for more details regarding these new waived tests.

Background

The Clinical Laboratory Improvement Amendments of 1988 (CLIA) regulations require a facility to be appropriately certified for each test performed. To ensure that Medicare & Medicaid pay only for laboratory tests categorized as waived complexity under CLIA in facilities with a CLIA certificate of waiver, laboratory claims are currently edited at the CLIA certificate level.

Change Request (CR) 3984 notifies Medicare carriers of the new waived CLIA covered tests which were approved by the FDA. Medicare carriers will update their files to include the new tests granted waived status under CLIA, and CR3984 includes the complete list of these tests as an attachment. To review the

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attachment to CR3984, please see the official instruction issued to your carrier by going to <http://www.cms.hhs.gov/Transmittals/downloads/R642CP.pdf> on the CMS web site.

The latest tests approved by the FDA as waived tests under the CLIA are listed below.

The Current Procedural Terminology (CPT) codes for the new tests in the following table must have the modifier QW to be recognized as a waived test.

CPT Code/Modifier	Effective Date	Description
86318QW	December 9, 2004	Germaine Laboratories, Aimstep H. pylori {whole blood}
87807QW	January 28, 2005	Binax Now RSV Test (K032166/A005)
81003QW	February 18, 2005	Physician Sales & Service, Inc. PSS Select Urine Analyzer
87880QW	March 8, 2005	McKesson Medi-Lab Performance Strep A Test Dipstick
86308QW	March 8, 2005	Clearview Mono-Plus II
86318QW	March 8, 2005	Wampole Laboratories Clearview H. pylori II (finger stick or whole blood)
87899QW	March 16, 2005	Genzyme OSOM Trichomonas Rapid Test
86308QW	March 16, 2005	McKesson Medi-lab Performance Infectious Mononucleosis Test
83721QW	March 25, 2005	Polymer Technology Systems Cardiochek PA Analyzer
87880QW	April 21, 2005	Biotechnostix Rapid Response Strep A Rapid Test Strip
87880QW	April 21, 2005	Biotechnostix Rapid Response Strep A Rapid Test Device
87880QW	April 21, 2005	RAC Medical Clarity Strep A Rapid Test Strips
80101QW	June 3, 2005	Acon One Step Multi-Drug, Multi-Line Screen Test Device (Professional Use)

Note: The tests mentioned on the first page of the Attachment included with CR3984 (i.e., CPT codes: 81002, 81025, 82270, G0107, 82962, 83026, 84830, 85013, and 85651) do not require a QW modifier to be recognized as a waived test.

Also note the following:

- New waived code **83721QW** has been assigned for LDL cholesterol testing performed using the Polymer Technology Systems Cardiochek PA Analyzer as of March 25, 2005; and
- New waived code **87899QW** has been assigned for Trichomonas testing performed using the Genzyme OSOM Trichomonas Rapid Test as of March 16, 2005.

For these two tests, your carrier will not search their files to 1) either retract payment or 2) retroactively pay claims. However, your carriers should adjust claims if you bring the claims to their attention.

Implementation

The implementation date for this instruction is October 3, 2005.

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Additional Information

For complete details, please see the official instruction issued by going to <http://www.cms.hhs.gov/Transmittals/downloads/R642CP.pdf> on the CMS web site.

If you have any questions, please contact your carrier at their toll-free number which may be found at <http://www.cms.hhs.gov/MLNProducts/downloads/CallCenterTollNumDirectory.pdf> on the CMS web site.

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